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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,789	03/16/1998	EDWARD LAWRENCE CARVER JR.	4537-01-2	9998

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EXAMINER

SODERQUIST, ARLEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/24/2003

41

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/039,789

Applicant(s)

CARVER ET AL.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-30,32-35,38 and 40-46 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 27-30,32-35,38 and 40-46 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. The request filed on December 4, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/039,789 is acceptable and a CPA has been established. An action on the CPA follows.
2. Claims 27-30,32-35,38 and 40-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for lysing the blood of different animal species by making mixtures of the blood and one or more of at least two lysing agents by changing the respective volumes of the lysing agent(s) and the blood sample dependent upon the animal species, does not reasonably provide enablement for for lysing the blood of different animal species by making mixtures of the blood and only a single lysing agent by changing the respective volumes of the lysing agent and the blood sample dependent upon the animal species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The instant specification teaches the presence of two lysing agents to make mixtures based on the animal species. Within the scope of these teachings, using any combination of the at least two lysing agents is enabled by the specification and its use of "and/or" in the paragraph bridging pages 8-9 and in the last paragraph of page 27. However, in the broadest interpretation of the claims, a single lysing agent is used to make all of the mixtures. The specification fails to teach that a single lysing agent can lyse all types of blood by changing the blood to lysing agent volume ratio. While a single lysing agent can be used for one or more of the samples, to lyse lyse the blood from all of the species requires the presence of at least two lysing agents from which one or more is selected and used to form the lyse/blood mixture. The specification further fails to teach or provide any basis for grouping blood samples into a set or analyzing a set of blood sample types that can be lysed by changing the lysing agent to blood volume ratio of a single lysing agent. Due to the difference of blood types recognized by the art of record, one of skill in the art would not expect a single lysing agent to be effective to lyse all blood types based on the teachings found in the instant specification. It also appears that a diluent is required to be present to form the lysing

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mixture since the lysing agents each have a constant concentration and the sensing apparatus requires a certain volume to run the analysis.

3. Applicant's arguments filed December 4, 2002 have been fully considered but they are not persuasive. In the sections of pages 8-9 and 27 of the specification referred to by applicant the use of "and/or" is clearly within the position on enablement that examiner has taken. The meaning is that the blood from any species may be lysed by creating a mixture using lysing agent A, lysing agent B or a combination of lysing agents A and B. This is different from lysing agent A can be used to lyse the blood of all species which examiner is interpreting as the broadest possible interpretation of the claims. Clearly, the instant specification fails to state that a single lysing agent can be used to lyse the blood of all animal species. Additionally, one of ordinary skill in the art, looking at the art would not have an expectation that a single lysing agent can be used to lyse the blood of all animal species based on their recognized differences. Further support for examiner's position can be found in the paragraph bridging pages 17-18. the database contains "information as to the predetermined volumes of lysing agent A and lysing agent B necessary to form the proper sample blood/reagent mixture for selected animal species (e.g., dog, cat, rat, mouse, horse, cow, rabbit, monkey, pig, goat, bird, etc.)" (emphasis added). Thus the database requires the presence of at least two lysing agents to make the proper mixtures for all species.

All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



March 20, 2003

ARLEN SODERQUIST
PRIMARY EXAMINER